REMARKS

Claims 20, 22-28, 31, 33, 36, 41-47 are pending in the present application. Claims 29 and 30 have been canceled without prejudice and without acquiescence. Applicants retain the right to file a continuation application on any canceled subject matter. No new matter has been added.

The issues outstanding in this application are as follows:

- Claims 29 and 30 are objected to because of informalities;
- Claim 20-26, 29-31, 33, 36, 42-47 was allegedly rejected under 35 U.S.C. § 103(a) as being unpatentable over Kellogg et al (US 6,143, 248) in view of Burns et al. (US 6,379,929);
- Claims 27-28 and 41 were allegedly rejected under 35 U.S.C. § 103(a) as being unpatentable over Kellogg et al., in view of Sheppard, Jr. et al., (US 6,142,247).

Applicants respectfully traverse the outstanding rejections, and Applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

I. Claim Objections

Claims 29 and 30 are objected to because of informalities. Applicants respectfully traverse.

In order to advance the prosecution of this application, Applicants have canceled claim 29 and 30 without prejudice and without acquiescence. In light of this amendment, Applicants request the objection to be withdrawn.

II. 35 U.S.C. § 103(a)

A. Claim 20-26, 29-31, 33, 36, and 42-47

Claim 20-26, 29-31, 33, 36, and 42-47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kellogg et al. in view of Burns et al. Applicants respectfully traverse.

Applicants agree with the Examiner, as stated in the Office Action of February 3, 2004, that Kellogg teaches only valving in microfluidic devices at areas of junctions between different sections of a microfluidic flow system, such as junctions between reservoirs and chambers. It is agreed that Kellogg does not teach the claimed hydrophobic patches within a microfluidic channel.

More specifically, Kellogg, including the passage cited by the Examiner, teaches stop-flow valving in a microfluidic flow system. The Kellogg specification teaches that this stop-flow valving depends on a change in the dimensions of the flow channel, the dimension change occurring at a junction (*see, e.g.*, col. 14, lns. 5-21 and Fig. 2B). As taught by Kellogg, in some embodiments, the type of dimension change depends on the wettability of the channels, for example, the specification teaches that in a non-wetting system (e.g., a channel having walls with a contact angle of >90°), a decrease in lateral (cross-sectional) dimension will be capable of stopping (valving) fluid flow, and in a wetting system (e.g., a channel having walls with a contact angle of <90°), an increase in lateral (cross-sectional) dimension will be capable of stopping (valving) fluid flow. (*Id.*)

Regarding the obviousness rejection, first, applicants assert that the obviousness rejection is improper because there is no suggestion or motivation to combine the references. While both references address microfluidic devices, Kellogg expressly teaches valving, while

Burns is not expressly addressed to valving. Instead, Burns is addressed to the creation of discrete droplets each having a well charactarized volume (e.g., metering), and movement of these droplets within a microchanel. For example, in describing the invention, the Burns specification states:

> The present invention contemplates methods, compositions and devices for the creation of microdroplets of discrete (i.e., controlled and predetermined) size. The present invention contemplates the use of selective hydrophobic coatings to develop a liquid-sample injection and motion system that does not require the use of valves.
>
> (col. 35, lns. 9-14).

Next, the obviousness rejection is improper because it relies on hindsight deconstruction, selection and combination in order to make the claimed invention. Specifically, the microfluidic device of Burns shows two ways for stopping liquid flow in the context of droplet creation (see Figs. 3-4): i) a hydrophobic (non-wettable) air channel (70), and ii) a hydrophobic patch (40). Burns repeatedly points out that their system for formation and motion of droplets does not require the use of valves. See e.g. column 35, lines 12-14. For valves comprising stopping and restarting the transport of droplets, Burns explicitly refers to sealed valves. See Column 44, lines 7-39.

Applicants assert that one skilled in the art examining Burns for improving the valve function of Kellogg would primarily focus on the passage in Burns where valves explicitly are discussed, i.e. sealed valves. This would certainly not lead to hydrophilization of the downstream end of the hydrophobic tube used in Kellogg (column 29, lines 20-28) in order to accomplish the present invention.

As discussed above, Kellogg teaches valving in a microfluidic system at junctions with changes in flow channel dimension and, optionally, combined with changes in wettablilty. Applicants respectfully assert that one skilled in the art examining Burns in light of Kellogg, might recognize that the stop for droplet transport at the junction of the hydrophobic air channel (70) with the through- passing hydrophilic transport channel (20) (See Fig. 3B) comprises an increase in a cross-sectional dimension. This is exactly what is demanded for a valve function according to Kellogg (see *e.g.*, col. 14, lns. 5-21 and Fig. 2B of Kellogg). However this kind of liquid stop in Burns functions in quite a different way

compared to the valve of Kellogg. The hydrophobic air channel (70) vents the driving gas over-pressure to ambient atmosphere once the droplet (60) has passed the junction. Due to lack of driving pressure the droplet will stop immediately after the junction. Due to the hydrophobicity of air channel (70) the droplet will pass into the hydrophilic transport channel (20). In order to restart the transport, the hydrophobic air channel (70) must be closed or some other transport system must be relied upon, e.g. the droplet motion system specifically described in Burns (see e.g. column 36, line 57, to column 37, line 63. This "junction-based" stop-flow valving of Burns is shown in Figs. 3B and 4B and is described in the specification, for example in column 35, line 60 through column 36, line 5. One skilled in the art would realize that making the outer part of the air channel (70) hydrophilic wouldn't change the function of the liquid stop of Burns.

Applicants respectfully also assert that one skilled in the art examining Burns would recognize that the liquid stop function defined by the hydrophobic patch (40)(140) in the droplet formation unit is not associated with any change in cross-sectional dimension. Therefore, one skilled in the relevant art would not view Burns, in light of Kellogg, and arrive at the claimed microfluidic CD device having a valve comprising a hydrophobic patch within a hydrophillic channel. While Burns arguably describes a hydrophobic region (40) within a hydrophilic channel (20), this is described as being an integral part of a larger, complex unit for the formation of well-defined droplets. For example, Figs. 3 and 4, and virtually the entire specification of Burns, describe a complex mechanism whereby fluids are moved in and out of a microfluidic device by at least three separate and distinct channels. Further, the result is a fluid droplet having a defined volume, not valving.

In order to combine the hydrophobic fluid region (40) of Burns with Kellogg to arrive at the claimed invention, one skilled in the art would be required to deconstruct the complex unit for the formation of well-defined droplets of Burns and select just one component, (40), for combination with Kellogg. There is no teaching or suggestion in either Kellogg or Burns to make such a deconstruction, selection and then recombination. Indeed, as discussed above, if one skilled in the art were to make any combinations of Burns in light of Kellogg, it would arguably be to combine the sealed valve or stop-flow valve (70) of Kellogg with Burns. This is especially true since Burns teaches a droplet formation mechanism, not a valving mechanism.

The present obviousness rejection is therefore improper as it is based on impermissible hindsight, requiring improper deconstruction, selection and combination.

B. Claims 27-28 and 41

Claims 27-28 and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kellogg et al., in view of Sheppard, Jr. et al., (US 6,142,247). Applicants respectfully traverse.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka,* 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Independent claim 31 requires hydrophilic pathways and a hydrophobic section within a hydrophilic pathway. Applicants agree with the Examiner, as stated in the Office Action of February 3, 2004, that Kellogg does not teach the claimed hydrophobic patches within a hydrophilic pathway. Further, Applicants assert that Sheppard Jr. also does not teach nor suggest hydrophilic pathways and a hydrophobic section within a hydrophilic pathway.

Since neither Kellogg et al. nor Sheppard Jr. et al. either separately or in combination teach or suggest all the limitations of independent claim 31, Applicants assert that this rejection is moot and dependent claims 27-28 and 41 are non-obvious since the dependent claims by definition contain all the limitations of the independent claim. Furthermore, if an independent claim is non-obvious under 35 U.S.C. 103(a), than any claim depending therefrom is by definition non-obvious. *In re Fine*, 5 USPQ 2d 2596 (Fed. Cir. 1988).

Accordingly, Applicants respectfully submit reconsideration and withdrawal of the outstanding rejection under 35 U.S. C. 103(a) as being unpatentable over Kellogg et al. in view of Sheppard, Jr. et al.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. 10104200 from which the undersigned is authorized to draw.

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Respectfully submitted,

By _____

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